

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

FILED

OCT 14 2008

[Signature]
CLERK

Davenport, Evans, Hurwitz & Smith, LLP,

Plaintiff,

vs.

Food and Drug Administration, Department of
Health and Human Services,

Defendant.

CIV. 08-4164

COMPLAINT

Plaintiff, Davenport, Evans, Hurwitz & Smith, LLP (DEHS) for its Complaint against the Defendant states and alleges as follows:

1. This is an action under the Freedom of Information Act (5 U.S.C. § 552), as amended ("FOIA") to order the production of agency records.
2. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a) 4(B).
3. Plaintiff DEHS, is a South Dakota limited liability partnership engaged in the practice of law within the state of South Dakota and elsewhere. It submitted the FOIA request which is the subject of this action.
4. Defendant Food and Drug Administration, Department of Health and Human Services, is an agency of the United States and has possession of the records which Plaintiff seeks.
5. By letter dated July 22, 2008, a copy of which is attached as **Exhibit A**, Plaintiff requested access under the FOIA to Defendant Food and Drug Administration, Department of Health and Human Services records prepared and maintained by the agency concerning reports of complications involving

life threatening complications associated with recombinant human bone morphogenetic protein (BMP) in cervical spine fusions. By letter dated September 23, 2008, a copy of which is attached as **Exhibit B**, Plaintiff requested copies of 208 reports of adverse events to the FDA concerning off-label uses of Infuse, a form of BMP.

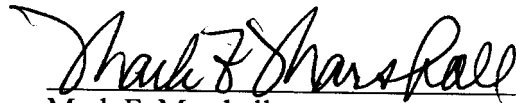
6. By letter dated July 24, 2008, a copy of which is attached as **Exhibit C**, Defendant Food and Drug Administration, Department of Health and Human Resources responded to Plaintiff's request by stating that it would respond as soon as possible. Defendant Food and Drug Administration, Department of Health and Human Services has yet to provide any responsive document to Plaintiff's requests and has not indicated when such a response might be forthcoming.
7. More than ten working days have passed since defendant Food and Drug Administration, Department of Health and Human Services' receipt of Plaintiff's FOIA requests and Defendant Food and Drug Administration, Department of Health and Human Services has not notified Plaintiff as to whether it will fully comply with Plaintiff's request. Thus under 5 U.S.C. § 552(a)(6)(A) and 5 U.S.C. § 552(a)(6)(C), Plaintiff has exhausted its administrative remedies.
8. Plaintiff has a right of prompt access to the requested documents under 5 U.S.C. § 552(a)(3), and there is no legal basis for denial of such access by Defendant Food and Drug Administration, Department of Health and Human Services.

Wherefore, Plaintiff requests that this court:

1. Expedite the action as provided in 5 U.S.C. § 552(a)(D);
2. Order Defendant Food and Drug Administration, Department of Health and Human Services to promptly make the documents available as requested;
3. Award Plaintiff its costs and reasonable attorney's fees in this action pursuant to 5 U.S.C. § 552(a)(4)(E);
4. And such other and further relief as the Court may deem just and appropriate.

Dated at Sioux Falls, South Dakota, this 14th day of October, 2008.

DAVENPORT, EVANS, HURWITZ &
SMITH, L.L.P.



Mark F. Marshall
206 West 14th Street
PO Box 1030
Sioux Falls, SD 57101-1030
Telephone: (605) 336-2880
Facsimile: (605) 335-3639
E-mail: mmarshall@dehs.com
Attorneys for Plaintiff